IMPACT ANALYSIS OF TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS) ON THE INDIAN PHARMACEUTICAL INDUSTRY

Synopsis

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1.0 INTRODUCTION

1.1 Pharmaceutical Industry in India

The Indian pharmaceutical industry has achieved production self-sufficiency and has been one of the largest drug exporters in the world since the late-1980s. It has also shown promising global competitiveness. The Indian pharmaceutical industry continues to expand across the world. This success has been attributed to the industry's ability to conduct research and development (R&D) and to develop generic drugs acquired and improved under the weak patent protection regime enabled by the Patent Act, 1970 from the 1970s to the 1990s. The Patent Act, which recognized process patents but not product patents, paved the way for advances in indigenous Indian R&D.

Indian pharmaceutical sector supplies over 50% of the global demand for various vaccines, 40% of the generic demand for US and 25% of all medicines for UK. India contributes the second-largest share of pharmaceutical and biotech workforce in the world. India's domestic pharmaceutical market is estimated at US$ 41 billion in 2021 and likely to reach US$ 65 billion by 2024 and further expand to reach ~US$ 120-130 billion by 2030[1]. (Indian Economic Survey 2021)

Globally, India ranks 3rd in terms of pharmaceutical production by volume and 14th by value (IBEF). The domestic pharmaceutical industry includes a network of 3,000 drug companies and ~10,500 manufacturing units. Indian drugs are exported to various countries in the world, with US being the key market. Generic drugs account for 20% of the global export in terms of volume, making the country the largest provider of generic medicines globally. It is expected to expand even further in the coming years.

1.2 Segments in Indian Pharmaceutical Sector

1. Active Pharmaceutical Ingredients (APIs)- The *main ingredient in Pharmaceutical is API [Active Pharmaceutical Ingredient]*. It is the main drug which cures the disease. There are many companies which produce and are specialist in only producing APIs. In producing APIs, the companies either purchase intermediates from different players and mix them to produce a final API or they themselves produce all the intermediates and mix at their own place.

2. Biosimilar- Biosimilar are medicines made from living cells through highly complex manufacturing processes and must be handled and administered under carefully monitored conditions.

Biosimilar are used to prevent, treat, diagnose, or cure a variety of diseases including cancer, chronic kidney disease, autoimmune disorders, and infectious diseases.

3. Formulations- Pharmaceutical formulation, in pharmaceutics, is the process in which different chemical substances, including the active drug, are combined to produce a final medicinal product. The word formulation is often used in a way that includes dosage form.

4. Contract Research and Manufacturing Services (CRAMS)- Pharmaceutical companies are increasingly outsourcing research activities to academic and private contract research organizations (CROs) as a strategy to stay competitive and flexible in a world of exponentially growing knowledge, increasingly sophisticated technologies and an unstable economic environment. Under high pressure to contain fixed costs, all drug companies are currently reducing their internal capacities in R&D, manufacturing, and even marketing and, instead, increasing their outsourcing. There are three broad outsourcing opportunities available to India – Custom Chemical Synthesis or CCS, clinical trials and contract manufacturing or CRAMS.

1.3 Policy Measures supporting growth of Indian Pharmaceutical Sector-

Table No.1- Government Initiatives

Support for technology upgrades and FDIs	In March 2017, the Government decided to create a digital platform to regulate and track the sale of quality drugs, and it can be used by people living in the country as well as abroad.
National Biopharma Mission	The industry - Academia mission was launched in June 2017 to boost development of biopharmaceuticals in India.
National Commission for Homeopathy (NCH) Bill, 2018	In December 2018, the Government of India approved the National Commission for Homoeopathy, Bill, 2018 in order to have more transparency in the sector.
Production linked incentives	In September 2020, the government announced production-linked incentive (PLI) scheme for the pharmaceutical industry worth Rs. 15,000 crore (US$ 2.04 billion). Source: Ministry of Commerce & Industry
Pharma Vision 2020	Pharma Vision 2020 by the Government's Department of Pharmaceuticals aims to make India a major hub for end-to-end drug discovery.
Pharmaceutical Parks	Government of India is planning to set up mega bulk drug parks in order to reduce industry's dependency on raw material imports.
Union Budget 2021-22	The Ministry of Health and Family Welfare has been allocated Rs. 73,932 crore (US$ 10.35 billion) and the Department of Health Research has been allocated Rs. 2,663 crore (US$ 365.68 billion). The government allocated Rs. 37,130 crore (US$ 5.10

	billion) to the 'National Health Mission'. PM Aatmanirbhar Swasth Bharat Yojana was allocated Rs. 64,180 crore (US$ 8.80 billion) over six years. The Ministry of AYUSH was allocated Rs. 2,970 crore (US$ 407.84 million), up from Rs. 2,122 crore (US$ 291.39 million). (India Brand Equity Foundation (IBEF))

Source: India Brand Equity Foundation (IBEF)

1.4 Export Performance of Indian Pharmaceutical Industry

India is the world's largest provider of generic medicines; the country's generic drugs account for 20% of global generic drug exports (in terms of volumes). Indian pharma companies are capitalising on export opportunities in regulated and semi-regulated markets. The export performance of Indian Pharmaceutical Industry is shown below-

Table no.2- Export Performance of Indian Pharmaceutical Industry

Year	Exports of Pharmaceuticals		Major Countries	Major Products
	In US$ million	In INR (crore)		
1985-86	129.0	157.86	USA	Generic drugs
1986-87	126.2	161.29		
1987-88	529.0	685.87		
1988-89	773.0	1119.46		
1989-90	1128.5	1878.93		
1990-91	1235.1	2216.05	Europe, Africa, USA, Asia	Formulations, generic drugs
1991-92	1400.7	3452.97		
1992-93	1148.0	3324.82		
1993-94	1373.1	4306.83		
1994-95	1762.9	5535.26		
1995-96	2169.2	7255.87		
1996-97	2497.4	8865.66	USA, Russia, UK, Canada	Generic Drugs
1997-98	2821.8	10487.14		
1998-99	2654.6	11168.08		
1999-00	3088.2	13381.81		
2000-01	3664.0	16738.65		
2001-02	3697.0	17631.77		
2002-03	4658.4	22544.58		
2003-04	5845.6	26861.56	USA, Europe	Formulations, Generic drugs
2004-05	6697.3	30092.07		
2005-06	8936.8	12219.51		
2006-07	10445.8	47266.6		
2007-08	13346.6	53734.3	USA, Germany, Russia, UK, China, Brazil, Canada	Bulk- drugs
2008-09	15628.4	71880.0		
2009-10	15767.5	74806.2	USA, UK, Russia, South Africa, Nigeria, Germany, Ukraine, Vietnam, Sri Lanka, Kenya	Formulations & Biologicals
2010-11	19241.1	87667.3	North America,	

2011-12	24439.9	1171.23	Europe, Japan, Asia, Africa, Australia, Latin America	Formulations & Biologicals, Bulk-Drugs, Intermediates
2012-13	27043.4	14471.43		
2013-14	27541.7	1666.32	USA, Russia, South Africa, UK, Nigeria, Germany, Kenya, Netherlands, Australia, Brazil	
2014-15	15430.9	943.50	USA, South Africa, UK, Australia, Germany	Bulk drugs, intermediates, formulations
2015-16	16883.6	1105.34		
2016-17	16829.4	1128.8		
2017-18	17282.4	1114.1		
2018-19	19146.9	133944		
2019-20	20702.7	146746	USA, Africa, European Union	Bulk drugs, intermediates, drug formulations, biologicals
2020-21	24443.8	181259	North America, Africa, EU, ASEAN, Middle East, Latin America	Bulk drugs, intermediates, drug formulations, biologicals

Source: Directorate General of Commercial Intelligence and Statistics.

Exports of Indian pharmaceuticals, including bulk drugs, intermediates, drug formulations, biologicals, AYUSH & herbal products and surgical products, reached US$ 16.28 billion in FY20. India's drugs and pharmaceuticals exports stood at US$ 20.14 billion in FY21[2]. (IBEF)

The biggest export destination for Indian pharma product is the US. In FY20, 32.1% of India's pharma exports were to the North America, followed by 17.96% to Africa and 15.70% to the European Union. India's formulation surged 18% and the bulk drug exports rose 9% y-o-y in the first half of FY21[3], according to a report by CRISIL.

1.5 Trade-Related Aspects of Intellectual Property Rights (TRIPS)

The TRIPS Agreement covers the issues of protection of intellectual property in trade-Related areas to a significant degree and is seen as a comprehensive new framework prescribing standards of intellectual property protection. Further, the TRIPS Agreement has the added significance of being the first international agreement concerning all types of intellectual property with numerous substantive provisions.

The negotiations concerning Trade-Related Aspects of Intellectual Property Rights (TRIPS) became one of the important new areas for discussion at the Uruguay Round of GATT, begun in 1986. Along with other agreements to come out of the Uruguay Round, the Agreement on Trade-Related Aspects of

Intellectual Property Rights (the TRIPS Agreement) was finally agreed upon at the ministerial meeting in Marrakesh, Morocco in April 1994, and came into force as part of the WTO Agreement on January 1, 1995.

In the intellectual property field there already existed several agreements for the international protection of intellectual property, such as the Paris Convention Related to industrial property rights including patents and trademarks, and the Berne Convention concerning copyright. However, with more emphasis being placed on the trade-Related Aspects of intellectual property, it was seen as an urgent task to attain international agreement in the context of GATT, with as many nations as possible participating, concerning standards of protection of intellectual property associated with trade.

1.6 Rationale behind Trade-Related Aspects of Intellectual Property Rights (TRIPS)

At present, the products of intellectual creativity such as inventions, designs, know-how and artistic works serve an important role, and in order to promote such creative activity, inventions, industrial designs, literary and artistic works, layout-designs of integrated circuits, trade secrets and so on are given protection. Furthermore, trademarks and other such signs are also protected to secure the trust obtained through business activities, as well as protect consumers and ensure fair competition.

Therefore, the negotiations concerning Trade-Related Aspects of Intellectual Property Rights (TRIPS) became one of the important new areas for discussion at the Uruguay Round of GATT in 1986.

The World Trade Organization's (WTO's) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) calls for the harmonization of intellectual property rights (IPRs) regulations across all WTO member countries. The TRIPS Agreement requires all WTO member countries to adopt and enforce minimum standards of intellectual property.

1.7 Overview of Indian Pharmaceutical Industry in Pre- TRIPS Period

The Indian pharmaceutical industry, which had little technological capacity to manufacture drugs indigenously in the 1950s, achieved production self-sufficiency and became one of the largest drug exporters in the world in the late 1980s. Driving the development of the industry was the weak patent regime of the Patent Act, 1970 and the Drug Policy, 1978. After India's independence, the Indian government appointed two committees, the Tek Chand Patents Enquiry Committee (1948 to 1950) and the Ayyangar Committee (1959), tasked with improving the accessibility and affordability of essential

drugs in India. These committees recommended amending the Designs and Patents Act, 1911, which recognized product patents for pharmaceuticals. This act was indeed replaced by the Patent Act, 1970. The Patent Act, 1970 recognized only process patents and reduced the patent period from 16 to 7 years. Automatic licences of right could be issued three years after the patent was granted. The act allowed Indian pharmaceutical companies to produce alternative processes for drugs that were not patented in India. From the 1970s to the 1980s, Indian companies began to take up R&D work on their own. The weak intellectual property protection regime provided under the Patent Act, 1970 was a turning point in the development of indigenous pharmaceutical R&D in India. The act encouraged reverse-engineering and the development of alternative processes for products patented in other countries. The Drug Policy, 1978 was India's first comprehensive drug policy. The basic objective of the policy was to achieve self-sufficiency in drug production.

2. REVIEW OF LITERATURE

A literature review is a comprehensive summary of previous research on a topic. Therefore, the researcher has compiled a list of reviews related to the topic of the study.

Manju., & Sharma, V. (2020)[4] to find out the trends in export and import of pharmaceutical products during pre and post TRIPS period. The study concludes that the export of drugs (formulations) is more than the imports of pharmaceutical products.

Kamiike, A. (2020)[5] explores how the TRIPS Agreement is influencing the Indian pharmaceutical industry and discusses the industry's growth factors in the post-TRIPS period within the GVC framework. The study concludes that TRIPS agreement led to change in the R&D orientation which further led in the increase of the R&D investments. Indian pharmaceutical firms have also upgraded by adopting state of the art technologies by being part of Global Value Chain (GVC).

Chawra, H.S. (2020)[6] studied the current scenario and opportunities on global pharma market and the Indian pharma market. The study stated that Indian pharma market will emerge much stronger in the transitionary phase as it has been successful in driving generics penetration globally and implementation of good policies, regulation, low cost of labor are the key factors that influence the industry.

M, Chitra., & Kumar, N. (2020)[7] the researchers attempted to view the status of existing Indian pharmaceutical market structure, government regulations, and common anti-competitive concerns in the sector. The study concludes that higher regulation may often reduce competition in the market. Therefore, a fine balance is needed between the regulations and competition.

Deo, S., & Franz, C. (2020)[8] analyses trade data of over 200 categories of health-Related goods, and provides quantitative evidence for the extent of many countries' health-Related import dependence on India. This report argues that the narrow discussion has fallen short in capturing India's crucial role in global health as a provider of health-Related goods to many developing countries. Given this position of India, this report concludes that the current health crisis calls for a comprehensive Indian global health strategy that will allow the country to expand on the existing multilateral system.

Motkuri, V., & Mishra, R.N. (2020)[9] entails to examine the structure and performance of domestic pharmaceutical industry and Indian market's pricing policy of drugs. Researchers found that the changes in the recent price policy are found to have certain leverage for the industry rather than affecting it. In the interest of social welfare, government intervention through price control of essential and life-saving drugs is a necessity for India.

Ray, et al. (2019)[10] tried to explore the evolution of market and export of pharmaceutical industry of India and Thailand. It is perceived that government needs to prepare an action plan for brand building around pharmaceutical sector. Also, a 'brand India' has gradually evolved around Indian pharmaceutical sector with the emergence of new segments of the industry, such as contract manufacturing, contract research services, biopharmaceuticals and Indian systems of medicines.

Dean, E.B. (2019)[11] this paper attempts to examine the theoretical and empirical effects of implementation of pharmaceutical price controls in India. This study concludes that the legislation resulted in broadly declining prices amongst both directly impacted products and competing products. Evidence was provided that the legislation impacted consumer types differentially and quality-sensitive consumers were benefitted the most, while the downsides largely affected poor and rural consumers which already suffer from low access to medicines.

Motkuri, V., & Mishra, R.N. (2018)[12] attempted to review the debates on the regulatory issues relating to the pharmaceutical industry in India and the perspectives of both the industry and the

advocates of health rights, especially the poor. It can be concluded from the study that as pharmaceutical industry involved with the phenomenon of Induced-demand and it is one of the industries where the price competition may not be prevailing, hence price controls on certain essential and life-saving drugs are needed in the Indian context.

Khurana, A. (2017)[13] investigated the role and impact of FDI in India and specifically study the pharmaceutical sector. The study concluded that the Indian Pharmaceutical Industry is positively impacted by FDI as it not only made India self-reliant but also a net exporter of generic medicines.

Lajipathirai, H., & Sekhar, B. (2017)[14] through this study researchers wanted to identify various strategies that would fit in pharmaceuticals to market their OTC product and to make an in-depth analysis of OTC products potency, safety and availability. The study derived at a conclusion to organize pharmaceutical industry, and those specially manufacturing over-the counter drugs or non-prescription drugs companies.

Banerji, A., & Suri, F.K. (2017)[15] have studied the impact of R&D expenditure, regulatory filings, and patents granted on exports from Indian Pharmaceutical industry. It can be concluded from the current study that Indian pharmaceutical exports are driven collectively by regulatory filings as well as total patents granted. It implies that in post TRIPS era and after the start of product patent regime; Indian pharmaceutical firms increased their R&D expenditure in order to enhance patenting activity and at the same time leveraged the opportunity of supplying generics to lucrative generic markets like USA and Europe.

Rentala, et al. (2017)[16] attempted to measure the export efficiency of Indian Pharmaceutical industry during transitory TRIPS and post TRIPS period by considering export efficiency as a measure of firm performance. The results indicated that the export efficiency of IPI has increasingly progressed after India became a member of WTO also the efficiency of the industry was higher during Post TRIPS. This had been possible since the industry was able to offer high-quality products at competitive prices.

Loitongbam., & Singh, B. (2016)[17] attempted to investigate the impact of TRIPS and RTAs on Indian pharmaceutical product exports. The researchers analysed how India achieves such a rapid rise in the pharmaceutical's exports in the world. To estimate the determinant of trade gravity model has been used. The study finds that the effect of partner countries' TRIPS implementation is negative and

significant on the IPI. It implies that India is shifting its pharmaceutical exports from regulated markets to unregulated markets. TRIPS implementation has greater impact on formulations exports than that on bulk exports. The RTAs have increased the export performance of India. It benefits more on formulations exports than bulk exports.

Loitongbam., & Singh, B. (2016)[18] examined the impact of globalization and IPR protection on the innovation in the Indian pharmaceutical industry, using the firm level panel data. This paper finds that there is a positive and highly significant level of foreign ownership effect on R&D activities. This indicates that there is technology spill over in the Indian pharmaceutical industry. TRIPS implementation has insignificant effects on R&D innovation. It is also found that exporting firms and firms with a higher productivity level are significantly more likely to carry out R&D activities.

Abrol, D., & Singh, N. (2016)[19] The paper analyses the post-TRIPS scenario in India and focuses on the impact of the approach adopted by governments for the formulation of post-TRIPS innovation policy to address the steering and coordination of policies for upgrading in-house R&D, publicly funded R&D, intellectual property, domestic industry and health system. Analysis further examines the contribution of in-house R&D activities of domestic pharmaceutical firms, foreign technology transfer through alliance making, and collaboration and overseas R&D (ORD) undertaken in India. Results indicate that the link between domestic firms and public sector research organisations is the weakest link of domestic pharmaceutical innovation system in India.

Rentala, et al. (2015)[20] this paper attempts to examine the determinants of export performance of Indian pharmaceutical industry ever since India became a signatory to the provisions of World Trade Organisation (WTO) in 1995. Quantile regression approach has been used. The results indicate that knowledge-based resources and property-based resources have a significant impact on the export performance of Indian pharmaceutical industry.

Rentala, et al. (2015)[21] presented a comparative analysis of the determinants of export performance of Indian pharmaceutical industry during the transitory-TRIPS (1995-2004) and post-TRIPS periods (2005-2014). The results indicate that various firm resources were more significant in the transitory TRIPS period in comparison to the post-TRIPS period in all the three models of export performance for the Indian pharmaceutical industry.

Rentala, et al. (2014)[22] in this paper the researchers tried to understand the significance of various technological capabilities and other firm resources that determine the export competitiveness of the Indian Pharmaceutical Industry. Analysis for research was done employing the ordinary least squares (OLS) regression method by comparison of results from the fixed effects model and random effects model. The results indicate that the R&D expenditures of Indian pharmaceutical firms still need to be increased to have a significant impact on export performance. Enhancement of technological capabilities will help the Indian pharmaceutical firms to introduce original research molecules in the international markets and help to increase the global competitiveness of Indian pharmaceutical industry.

Tyagi, et al. (2014)[23] examined the trends in exports, imports, R&D performance and patents applied for and granted especially after the TRIPS agreement in regard of Indian drug and pharmaceutical industry for the period 2000-2012. In order to determine the impact of innovation on exports in the Intellectual Property Rights framework, R&D expenditure and aggregate patent counts are taken into consideration. The study concluded that the growth rate of India's pharmaceutical exports has outweighed the corresponding growth rate of all other merchandize products, while imports have seen a declining trend.

Manisha (2014)[24] attempted to study the competitiveness of pharmaceutical exports and to comprehend the composition and direction of India's pharmaceutical exports with its two top export partners i.e., USA and Russia. Indices like Revealed Comparative Advantage (RCA), Revealed Symmetric Comparative Advantage (RSCA) and Intra Industry Trade (IIT) during 1991-2012 have been considered. The empirical result of the study revealed that India has revealed comparative advantage in maximum pharmaceutical products with these two countries. The positive correlation of R&D expenditure and exports has been found in Indian Pharmaceutical companies.

Vyas, et al. (2013)[25] The paper attempts to examine the role of mergers and acquisitions (M&A) and technological efforts in determining the export competitiveness of firms belonging to the pharmaceutical sector in India. M&A provides synergistic gains to firms. The results indicate that acquisition of technological capabilities either by in-house R&D or through imports of embodied or disembodied technology is an important determinant of firms' competitiveness in international market.

Akhtar, G. (2013)[26] attempted to analyse Indian pharmaceutical industry especially the balance of trade, bulk drugs & formulations and TRIPS. The results concluded that 70% of requirement of the country in bulk drugs and almost all the demands for formulations are met by the domestic industry. In addition to catering to the needs of the domestic demand it is also the leading supplier of bulk drugs and cheap formulations to the world and engaged in contract manufacturing contract research, clinical trials, contracts R&D.

Bedi, et al. (2013)[27] studied the impact of a restructured patent regime on the R&D expenditure and the patenting activity of Indian pharmaceutical companies. The results concluded that there has been a growth in patent activities in India after TRIPS came into existence.

Rentala, S., & Anand, B. (2013)[28] the study aimed at identifying relation between export marketing strategies and export performance of Indian pharmaceutical companies. Conceptual framework is designed to identify the impact of number of markets served, number of product categories offered and impact of marketing mix on export performance of the firm in the context of pharmaceutical companies in India. The findings of the study state that larger companies tend to perform better in export market.

Abrol, et al. (2011)[29] reflect on strategies adopted for learning, competence building and innovation and for creating complementarities and linkages within India's pharmaceutical industry during the post- Trade Related Intellectual Property Rights (TRIPs) period. The research came to a conclusion that Indian state and business have chosen globalization pathways with specific implications for innovation. There has been a significant change in domestic and foreign pharmaceutical firms reflected in outcomes of their R&D investment activities.

Joseph, R.K. (2011)[30] this discussion paper provides an analysis of the impact of these reforms on pharmaceutical R&D in India. It looks into the context in which the reforms were introduced, the nature and trends of R&D efforts and emerging R&D strategies. The analysis of R&D expenditure of pharmaceutical firms shows that there had been a growth in the R&D intensity since 2000-01, but this began to decline or stagnate after 2005-06.

Chadha, A. (2009)[31] This paper studies the product cycle and neo-technology theories of trade in the context of generic pharmaceuticals. It analyses the export performance of 131 Indian pharmaceutical

firms for the period 1989–2004. The results indicate that technology proxied by foreign patent rights has a positive impact on exports.

Kiran, R., & Mishra, S. (2009)[32] examined the impact of new Patent Act on Pharmaceutical Industry of India especially on R&D. This paper seeks to evaluate the performance of a few leading Pharmaceutical Firms especially in terms of their ANDA filings and approvals as well as DMF filings with USFDA in post-TRIPS period. The period of the 1995-2008, i.e., the post-TRIPS period saw the strongest performance of the Indian pharmaceutical industry as it was a powerhouse of API production. Indian companies have been at the forefront, both in terms of DMF and ANDA filings.

Nauriyal, D. (2006)[33] this article traces the history and the current profile of the Indian pharmaceutical industry taking in consideration the prominent changes in the new Act over the last Patents Act of 1970 and analysed the impact of such changes. The study concludes that leading players in the industry are likely to adopt a combination of 'cooperate and compete' strategies to adopt research-based tactics.

Pradhan, J.P. (2006)[34] explored the trends in the global competitiveness of the Indian pharmaceutical industry taking in consideration the productivity, R&D and trade performance. The conclusion of the study is that policy measures are needed to encourage mergers and acquisitions among domestic firms to offset the scale disadvantage and to overcome the trap of low R&D intensity.

Khanna, & Chand, N. (2002)[35]**,** this study gives the historical backdrop, present status, growth projections, export opportunities and changing strategies in the face of WTO. The study of the 57 pharmaceutical companies revealed that domestic companies have performed better than the MNCs mainly due to successful export business. Also, domestic formulation market is expected to continue to witness a squeeze on margins.

3. RESEARCH GAP AND NEED OF THE STUDY

1. There were very few studies where the rationale of Trade Related Aspects of Intellectual Property Rights (TRIPS) has been discussed, therefore, the proposed study attempts to discuss the rationale of TRIPS for Indian pharmaceutical industry in present scenario.

2. There were very few studies which are discussing the R&D pattern in Indian Pharmaceutical industry in post-TRIPS regime. The proposed study includes the R&D expenditure of Pre and post TRIPS regime and tries to find out is there any significant change in R&D pattern.

3. Most of the studies supported innovation led exports growth hypothesis despite the fact that Indian firms have been mainly exporting generic versions of patented products to developed markets and that the share of patented products in their export profile is negligible. It is therefore, important to include regulatory filings as one of the key factors which leads in export performance during TRIPS regime.

4. RESEARCH QUESTIONS

The proposed study will try to find the answers to the following research questions:

1. Are the government policies in line with Trade Related Aspects of Intellectual Property Rights (TRIPS)?
2. Is there any negative impact of Trade Related Aspects of Intellectual Property Rights (TRIPS) on Indian Pharmaceutical Industry?
3. Is there any significant contribution of Trade Related Aspects of Intellectual Property Rights (TRIPS) to boost the exports in Indian Pharmaceutical Industry?
4. Is there any significant change in Indian government policies for Indian Pharmaceutical Industry after the adoption of The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)?
5. Is there any significant change in scenario of Indian Pharmaceutical Industry before and after Trade Related Aspects of Intellectual Property Rights (TRIPS)?
6. Is there any significant change in R&D expenditure of Indian Pharmaceutical Industry due to Trade Related Aspects of Intellectual Property Rights (TRIPS)?
7. Is there any significant change in employment opportunities created by Indian Pharmaceutical Industry during Trade Related Aspects of Intellectual Property Rights (TRIPS) regime?

5. OBJECTIVES OF THE STUDY

Based on above reviews and need of the study the researcher has made certain objectives which are listed below-

1. To study the past and present performance (export performance, R&D expenditure, employment opportunities) of Indian Pharmaceutical Industry.
2. To study Trade-Related Aspects of Intellectual Property Rights (TRIPS)- Its rationale and provision adopted by Indian Pharmaceutical Industry.
3. To evaluate the impact of Trade-Related Aspects of Intellectual Property Rights (TRIPS) on Indian Pharmaceutical Industry.
4. To study the government regulations for Indian Pharmaceutical Industry.
5. To suggest the action plan for exploring global opportunities after TRIPS.

6. HYPOTHESES OF THE STUDY

$H_0$1: The government policies for Indian Pharmaceutical Industry are not in line with Trade- Related Aspects of Intellectual Property Rights (TRIPS).

$H_0$2: There is no significant negative impact of Trade- Related Aspects of Intellectual Property Rights (TRIPS) on Indian Pharmaceutical Industry.

$H_0$3: There is no significant contribution of Trade- Related Aspects of Intellectual Property Rights (TRIPS) to boost the exports of Indian Pharmaceutical Industry.

$H_0$4: There is no significant change in Indian government policies for Indian Pharmaceutical Industry after the adoption of Trade- Related Aspects of Intellectual Property Rights (TRIPS).

$H_0$5: There is no significant change in scenario of Indian Pharmaceutical Industry before and Trade-Related Aspects of Intellectual Property Rights (TRIPS).

$H_0$6: There is no significant change in R&D expenditure of Indian Pharmaceutical Industry due to Trade- Related Aspects of Intellectual Property Rights (TRIPS).

$H_0$7: There is no significant change in employment opportunities created by Indian Pharmaceutical Industry during Trade- Related Aspects of Intellectual Property Rights (TRIPS) regime.

7. RESEARCH DESIGN AND METHODOLOGY

7.1 SOURCES AND TOOLS OF DATA COLLECTION: The nature of study is such that it requires both primary and secondary data.

Primary Data: To collect the primary data, the industry survey will be conducted. Data will be collected from the top executives of the industry to find out their future plan and to assess the impact

of TRIPS on the Indian Pharmaceutical Industry. This survey will help to find out the future prospects of the industry.

Secondary Data: The secondary data will be collected from the reports of different committees framed by government, institutions (Department of Pharmaceuticals, India Brand Equity Foundation, Organisation of Pharmaceutical Producers of India) and the journals Related to Indian Pharmaceutical Industry. In addition to this, the work published by other scholars in form of research papers, PhD reports etc. will be reviewed time to time.

7.2 DURATION OF THE STUDY: This study will be divided into two parts i.e., Pre-TRIPS and Post-TRIPS. A window of 20 years is selected (Manju and Sharma V, 2020) and the researcher will take into consideration the period from 1985-2005 for Pre- TRIPS. For Post-TRIPS period of 2005 onwards will be taken into consideration.

7.3 SCOPE OF THE STUDY: For the present study Indian Pharmaceutical industry will be taken into consideration to analyse the impact of Trade- Related Aspects of Intellectual Property Rights (TRIPS) on the Indian Pharmaceutical Industry.

7.4 UNIVERSE AND SAMPLE SIZE: For the proposed study, all manufacturing units of the Indian Pharmaceutical industry will be the universe of the study. According to the Department of Pharmaceuticals (Ministry of Chemicals and Fertilizers) and India Brand Equity Foundation (2021), there are 10,500 no. of manufacturing units working in India. Out of 10,500 units, the researcher will choose 50 units of pharma industry based on systematic random sample. For this purpose, the researcher will consider only those 50 units as sample in the study that are having maximum export earnings, R&D expenditure during last 3 years, at the time of data collection.

7.5 VARIABLE OF THE STUDY: The researcher finds the number of variables that are divided independent and independent variables. The diagram below shows the same-

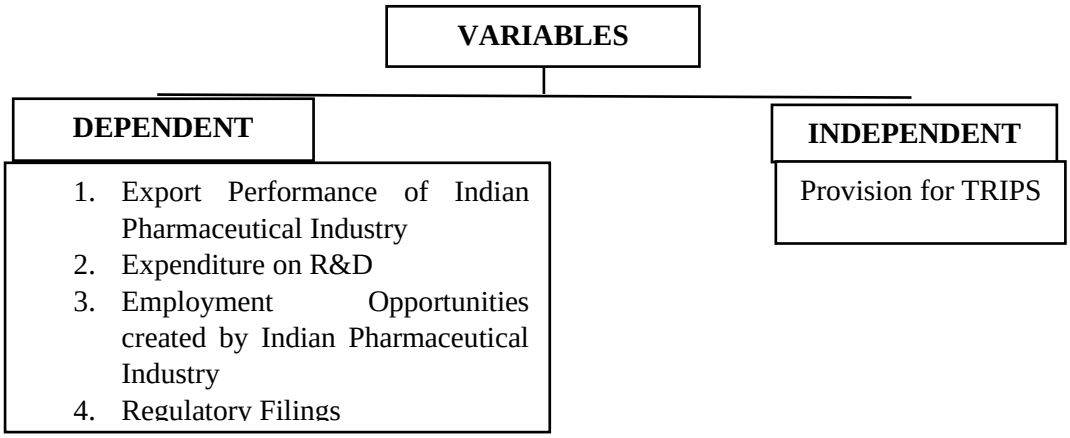

Fig. 1 Variables of the Study

7.6 STATISTICAL TOOL FOR ANALYSIS: Both types of statistical techniques i.e., descriptive and inferential statistics will be used to get reliable results and inferences. Tools like Factor analysis, Time Series analysis, Regression model, t-test, ANOVA, Chi- square test etc. shall be used for analysing the data as per the nature of data and requirement of the study.

7.7 RESEARCH METHODOLOGY

Table No.3- Objective wise methodology

OBJECTIVES	METHODOLOGY TO BE FOLLOWED
1. To study the past and present performance of Indian Pharmaceutical Industry.	For achieving this objective, the researcher will collect the information from different institutional websites and reports regarding Indian Pharmaceutical industry.
2. To study Trade-Related Aspects of Intellectual Property Rights (TRIPS)- Its rationale and provision adopted by Indian Pharmaceutical Industry.	For achieving this objective, researcher will use reports and documents of government websites like Central Drugs Standard Control Organisation (CDSCO), The National Pharmaceutical Pricing Authority (NPPA) and other authentic institutions to know the various policies adopted by the Indian Pharmaceutical industry in compliance with TRIPS.
3. To evaluate the impact of Trade-Related Aspects of Intellectual Property Rights (TRIPS) on Indian Pharmaceutical Industry.	Hypotheses will be tested on the basis of different statistical tools for evaluating the impact of TRIPS through export performance, R&D expenditure, employment opportunities and change in policy framework as dependent factors.
4. To study the government regulations for Indian Pharmaceutical Industry.	To achieve this objective, the researcher will collect the information from portals like Department of Pharmaceuticals, India Brand Equity Foundation (IBEF), Annual Survey of Industries (ASI) and Office of Controller General of Patents, Designs and Trademarks (CGPDTM).
5. To suggest the action plan for exploring global opportunities after TRIPS.	Based on the analysis, an action plan of suggestive measures will be formulated.

8. SOCIAL RELEVANCE OF THE STUDY

This research will evaluate the performance of pharmaceutical industry and the impact of TRIPS. This research will also examine the R&D efforts of the industry which is crucial for providing the quality medicines at reasonable price to Indian consumers. The R&D will also reduce the dependency of the industry on foreign companies. Through this, ultimately the Indian consumers will be benefited. By this study, the researcher feels that the impact of the TRIPS will help to expand the Indian pharmaceutical industry and make its global presence. The industry has shown it in case of preparation of vaccine against the COVID-19. The expansion of the industry will create better job opportunities in R&D area and others. At last, the researcher feels that while giving holistic interpretation to TRIPS agreement public health should be the prime consideration rather than merely protecting the interest of the companies.

9. PROPOSED CHAPTER PLAN OF THE STUDY

Chapter 1: - An Introduction of Study

Chapter 2: - Review of Literature, Research Gaps and Need of the Study

Chapter 3: - Research Design & Methodology

Chapter 4: - Data Analysis

Chapter 5: - Results and Findings

Chapter 6: - Conclusion and Suggestions

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